K102018

1. 510(k) Summary

Sponsor:	Synthes Biomaterials 1230 Wilson Drive West Chester, PA 19380
Company Contact	Jeffrey L. Dow, JD Director, Clinical & Regulatory Affairs Synthes Biomaterials 484 356 9720 dow.jeff@synthes.com
Date Summary Prepared	August 25, 2010
Device Name:	Norian Reinforced™ and Norian Reinforced Fast Set Putty™
Classification:	Class II, 21 CFR §882.5300 Methyl Methacrylate for Cranioplasty
Product Code	GXP
Predicate Devices:	Norian CRS Bone Cement (973789) Norian CRS Fast Set Putty (K012589)
Device Description:	Norian Reinforced and Norian Reinforced Fast Set Putty (FSP) are moldable, biocompatible bone cements with added reinforcing fibers. Norian Reinforced and Norian Reinforced FSP are intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton. The material resists cracking during the setting process. When fully cured, the composition formed closely approximates the mineral phase of bone. The product is available in two delivery forms. Norian Reinforced is an injectable paste that is mixed with an automatic mixer, and Norian Reinforced Fast Set Putty is manually mixed with a cup and spatula. Norian Reinforced is provided in a sterile pouch ("Rotary Pouch"). The Rotary Pouch is constructed of a clear-film outer pouch and a foil laminate inner pouch with an attached delivery syringe. The Rotary Pouch contains sterile powder with fibers and is designed with an injection port for the purpose of adding the mixing solution to the pouch. The mixing solution is contained in the Solution Syringe that is packaged separately.

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The Rotary Pouch is designed to be placed in an automatic reusable mixer outside the sterile field where the two components are mixed together to form a smooth, viscous paste. The paste remains injectable for approximately 5 minutes at 18°-23°C / 64°-73°F. At body temperature (37°C / 98.6°F), Norian Reinforced begins to harden after 2 minutes and sets in approximately 10 minutes.
Norian Reinforced is slowly resorbed over a period of years and replaced with bone during the healing process.

Norian Reinforced Fast Set Putty is supplied in two containers. The mixing cup holds sterile powder with fibers and the solution syringe holds sterile solution. When the powder and solution are mixed together with the provided cup and spatula, the resultant putty material can be manipulated for two minutes at 18°-23°C / 64°-73°F.

At body temperature (37°C / 98.6°F), Norian Reinforced *Fast Set Putty* begins to harden after 2 minutes and sets in approximately 3 to 6 minutes. Norian Reinforced *Fast Set Putty* is slowly resorbed over a period of years and replaced with bone during the healing process.

The results from mechanical and *in vitro* comparative testing demonstrate that Norian Reinforced Products are equivalent to the predicate Norian products previously identified. The material has been tested for safety following the biocompatibility standards set forth in ISO 10993. This testing demonstrates that Norian Reinforced Products pass the relevant tests specified, as did the predicates.

Intended Use: Norian Reinforced and Norian Reinforced Fast Set Putty are indicated for repairing or filling cranial defects and craniotomy cuts with a surface area no larger than 25 cm^2. Norian Reinforced and Norian Reinforced Fast Set Putty are also indicated for the restoration or augmentation of bony contours of the cranial skeleton (including fronto-orbital areas) such as burr hole voids and other cranial defects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes Biomaterials
c/o Jeffrey L. Dow, JD
Director, Regulatory & Clinical Affairs
1230 Wilson Drive
West Chester, PA 19380

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Re: K102018
Trade/Device Name: Norian Reinforced™ and Norian Reinforced Fast Set Putty™
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: July 14, 2010
Received: July 19, 2010

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. Indications for Use

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510(k) Number (if known): K102018

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Indications:

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Prescription Use ___X___	AND/OR	Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mendhika Vimani 9/15/10

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number 102018